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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,464	08/25/2003	James D. Ralph	F-286	8288
51640	7590	09/22/2006	EXAMINER	
SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/648,464

Applicant(s)

RALPH ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-16,18,20,21 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-16,18,20,21 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 28, 2006 has been entered.

Terminal Disclaimer

2. The terminal disclaimer filed on June 26, 2006 (re-filed on August 28, 2006) disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,863,689, and US patent application 10/140,153 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Amendment

3. Applicants' amendment of claims 13, 16, and 21 in the reply filed on August 28, 2006 is acknowledged.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 13-16, 18, 21, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xavier et al. (US 6,063,121 A) in view of Stubstad et al. (US 3,867,728 A; cited in Applicants' IDS).

As seen in Figures 1-5, Xavier et al. disclose an intervertebral spacer device (10) comprising first (20) and second (48) plate members, each having an external plate surface thereof, wherein an inner surface of one of said plate members comprises a ball-shaped structure (ball supporting member 42 + ball 46, or ball 46 by itself) extending therefrom and an inner surface of the other one of said plate members has a spring (**first interpretation:** socket supporting member 62 and socket 68; **second interpretation:** cushion 80; **third interpretation:** socket supporting member 62 + socket 68 + cushion 80) affixed thereto, said spring having an opening/curvate volume (**first interpretation:** socket 68; **second interpretation:** central aperture 90; **third interpretation:** socket 68 + central aperture 90). Xavier et al. disclose socket supporting member 62, socket 68, ball supporting member 42, and ball 46 as made from either metal or ceramic (see column 4, lines 50-64), and able to counteract the load applied to at least one of the plate members (see column 4, lines 11-20).

Xavier et al. did not particularly disclose said external plate surfaces as having a deflectable/deformable surface (or mesh) thereon. However, this is well known in the art. For example, Stubstad et al. disclose (see Figures 1, 2, and 4) an intervertebral spacer device (device 10) comprising: (i) first (top element 11) and second (bottom element 12) plate members, each having an external plate surface, at least one of the external plate surfaces having a deflectable/movable (i.e., capable of being deflected/moved; see column 8, lines 46-49; column

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9, lines 14-17), convex (see Figure 4; see column 13, lines 24-26), wire mesh (e.g., Dacron mesh 21 and/or Dacron mesh 20; see column 8, lines 6-10 and lines 43-59; column 9, lines 10-18). The device further comprises a force-restoring element (e.g. core 15) disposed between the first and second plate members (see entire document). Stubstad et al. teach said deflectable/deformable, convex wire mesh disposed on said external plate surfaces in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces (see columns 8 and 9). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an intervertebral spacer device comprising external plate surfaces having a deflectable/deformable, convex wire mesh thereon, as taught by Stubstad et al., with the intervertebral spacer device of Xavier et al., in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces.

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ralph et al. (US 5,989,291; previously cited in PTO-892) in view of Stubstad et al. (US 3,867,728 A; cited in Applicants' IDS).

As seen in Figures 3b, 4, 5, and 7-9, Ralph et al. disclose an intervertebral spacer device comprising first and second plate members (e.g., 100a, 100b), each having an external plate surface (e.g., 102a, 102b) thereof, the plate members being disposed such that the external plate surfaces face in opposite directions. Ralph et al. disclose plate members 100a, 100b as convex (see column 2, lines 61-63) and as having a porous coating (see column 3, lines 4-6; column 5, lines 57-61). Additionally, Ralph et al. teach a porous, resilient/flexible (i.e., deflectable; see

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column 3, lines 8-18; column 6, lines 17-21), and convex (see Figures 4 and 9) fabric/mesh (circumferential wall 120) on an external lateral portion of the intervertebral spacer device (see Figures 4, 6, and 9).

The ball attached with one of the plates is ball-shaped head 207. The socket (i.e., hollow part, or opening) affixed with the other one of said plates is the socket/opening shown in Figure 9. The claim language does not require the ball as received within the socket.

Although Ralph et al. disclose the external plate surfaces as convex to match the contour of the opposing bone surface (see column 2, lines 61-65), and a porous coating on said external plate surfaces to provide for tissue ingrowth (see column 3, lines 4-6; column 5, lines 57-61), they did not particularly disclose said external plate surfaces as having a deflectable/deformable surface (or mesh) thereon. However, this is well known in the art. For example, Stubstad et al. disclose (see Figures 1, 2, and 4) an intervertebral spacer device (device 10) comprising: (i) first (top element 11) and second (bottom element 12) plate members, each having an external plate surface, at least one of the external plate surfaces having a deflectable/movable (i.e., capable of being deflected/moved; see column 8, lines 46-49; column 9, lines 14-17), convex (see Figure 4; see column 13, lines 24-26), wire mesh (e.g., Dacron mesh 21 and/or Dacron mesh 20; see column 8, lines 6-10 and lines 43-59; column 9, lines 10-18). The device further comprises a force-restoring element (e.g. core 15) disposed between the first and second plate members (see entire document). Stubstad et al. teach said deflectable/deformable, convex wire mesh disposed on said external plate surfaces in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces (see columns 8 and 9). Therefore, it would have been

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obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an intervertebral spacer device comprising external plate surfaces having a deflectable/deformable, convex wire mesh thereon, as taught by Stubstad et al., with the intervertebral spacer device of Ralph et al., in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces.

7. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd et al. (US 5,425,773 A) in view of Stubstad et al. (US 3,867,728 A; cited in Applicants' IDS).

As seen in Figures 5 and 6, Boyd et al. disclose an intervertebral spacer device comprising first and second plate members, each having an external plate surface thereof, the plate members being disposed such that the external plate surfaces face in opposite directions, at least one of the external plate surfaces having a convexly shaped (see column 9, lines 1-6) porous coating (see column 9, line 52 to column 10, line 2). Boyd et al. also disclose a ball-shaped structure (e.g., ball 146) to be received and hold within a curvate volume (e.g., socket 126).

Although Boyd et al. disclose the external plate surfaces as convex to match the contour of the opposing bone surface, and a porous coating on said external plate surfaces to provide for tissue ingrowth, they did not particularly disclose said external plate surfaces as having a deflectable/deformable surface (or mesh) thereon. However, this is well known in the art. For example, Stubstad et al. disclose (see Figures 1, 2, and 4) an intervertebral spacer device (device 10) comprising: (i) first (top element 11) and second (bottom element 12) plate members, each having an external plate surface, at least one of the external plate surfaces having a

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deflectable/movable (i.e., capable of being deflected/moved; see column 8, lines 46-49; column 9, lines 14-17), convex (see Figure 4; see column 13, lines 24-26), wire mesh (e.g., Dacron mesh 21 and/or Dacron mesh 20; see column 8, lines 6-10 and lines 43-59; column 9, lines 10-18). The device further comprises a force-restoring element (e.g. core 15) disposed between the first and second plate members (see entire document). Stubstad et al. teach said deflectable/deformable, convex wire mesh disposed on said external plate surfaces in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces (see columns 8 and 9). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an intervertebral spacer device comprising external plate surfaces having a deflectable/deformable, convex wire mesh thereon, as taught by Stubstad et al., with the intervertebral spacer device of Boyd et al., in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces.

8. Claim 13-16, 18, 20, 21, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington (US 5,893,889 A; cited in Applicants' IDS) in view of Stubstad et al. (US 3,867,728 A; cited in Applicants' IDS).

As seen in Figure 2, Harrington discloses an intervertebral spacer device (18) comprising first (upper member 32, having base 49) and second (lower member 34) plate members, each having an external plate surface thereof, wherein an inner surface of one of said plate members comprises a ball-shaped structure (ball 46) extending therefrom and an inner surface of the other one of said plate members has a spring (**first interpretation:** annular collar 54; **second**

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interpretation: annular shock absorbing member 68; **third interpretation:** annular collar 54 + annular shock absorbing member 68; **fourth interpretation:** shock absorbing plug 69; **fifth interpretation:** annular shock absorbing member 68 + shock absorbing plug 69) affixed thereto (annular collar 54 is affixed to base 49 with screws 64, 66; annular shock absorbing member 68 is affixed once the prosthesis is assembled since the frustoconical surfaces prevents physical separation; shock absorbing plug 69 is affixed to base 49), said spring having an opening/curvate volume (**first interpretation:** central aperture of annular shock absorbing member 68; **second interpretation:** central aperture of annular collar 54, including neck 57; **third interpretation:** central apertures of annular collar 54 + annular shock absorbing member 68 combined).

Harrington did not particularly disclose said external plate surfaces as having a deflectable/deformable surface (or mesh) thereon. However, this is well known in the art. For example, Stubstad et al. disclose (see Figures 1, 2, and 4) an intervertebral spacer device (device 10) comprising: (i) first (top element 11) and second (bottom element 12) plate members, each having an external plate surface, at least one of the external plate surfaces having a deflectable/movable (i.e., capable of being deflected/moved; see column 8, lines 46-49; column 9, lines 14-17), convex (see Figure 4; see column 13, lines 24-26), wire mesh (e.g., Dacron mesh 21 and/or Dacron mesh 20; see column 8, lines 6-10 and lines 43-59; column 9, lines 10-18). The device further comprises a force-restoring element (e.g. core 15) disposed between the first and second plate members (see entire document). Stubstad et al. teach said deflectable/deformable, convex wire mesh disposed on said external plate surfaces in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces (see columns 8 and 9). Therefore, it would have been

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obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an intervertebral spacer device comprising external plate surfaces having a deflectable/deformable, convex wire mesh thereon, as taught by Stubstad et al., with the intervertebral spacer device of Harrington, in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces.

Conclusion


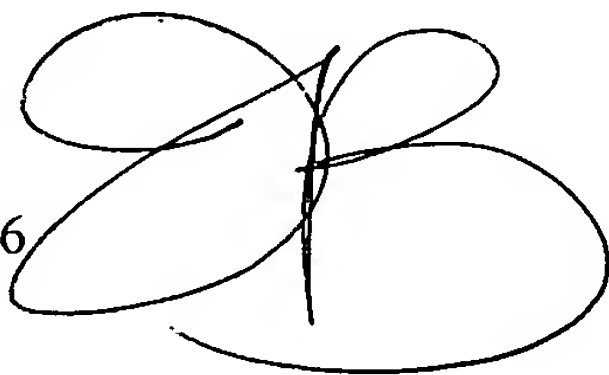
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Schug et al. (EP 599419), and Steffen (DE 10130825).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

September 7, 2006



David H. Willse
Primary Examiner